



April 1, 2005

Gary M. Jackson
Assistant Administrator for Size and Standards
Office of Size Standards
Small Business Administration
409 Third Street, SW
Washington, D.C. 20416

Re: Proposed Rulemaking Affecting SBIR Funding

Dear Mr. Jackson:

Thank you for the opportunity to comment on the Small Business Administration's (SBA) Advance Notice of Proposed Rulemaking (ANPRM) regarding the participation of businesses in the Small Business Innovation Research (SBIR) program that are majority-owned by one or more venture capital companies (VCC). I am writing on behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market. More than 200 device manufacturers comprise our membership, including makers of medical devices, diagnostic products, and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of technology and fostering the availability of innovative products in the marketplace and to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

As you know, in 2003 the SBA reinterpreted the eligibility requirements for SBIR grants. In order to qualify for a SBIR grant a business must be "small" (less than 500 employees) and "at least 51 percent owned and controlled by one or more individuals." However, the SBA's Office of Hearings and Appeals determined that the term "individuals" referred only to people and not to VCs, thereby making small businesses that are majority owned by venture capital firms ineligible for SBIR grants.

MDMA is concerned about this policy which does not allow manufacturers backed by venture capital funding to be eligible for SBIR grants. This interpretation is at odds with the program's intent to benefit U.S. small businesses. Making VC-backed companies ineligible for SBIR grants hinders innovation, especially among smaller companies that are performing much of the industry's research and development of new products. Furthermore, the most promising small manufacturers are the ones most likely to have VC support. These companies should not be penalized by the government and denied SBIR grants.

The current interpretation of SBIR eligibility is based on a strict reading of the program's regulations. This regulation was meant to prevent subsidiaries of large companies from being eligible for SBIR grants, not to limit awards based on a company's VC-backing.

While MDMA understands the 51% Rule now allows an SBIR award recipient to be owned by a VCC, as long as the VCC is itself owned and controlled by U.S. individuals, applicants who meet the ownership criteria in the 51% Rule, however, are still subject to SBIR size standards, most significantly, limiting the number of employees of the applicant and its affiliates to 500.

MDMA applauds the SBA's recognition in the 51% Rule that a business concern can be technically both majority-owned by VCCs and still eligible to receive an SBIR award; however, it does not fully accomplish the goals of Small Business Innovation Development Act (SBIDA), since the majority of limited partners in a VCC are not individuals even if in such cases, as in pension funds, they represent the interests of individuals.

In order to ensure that small innovative manufactures are not penalized for being VC funded and to continue to increase innovation and small business job creation, it is imperative that venture investment and SBIR funding not be mutually exclusive but work in a symbiotic fashion to promote the goals of SBIDA. The best way to correct this policy would be to articulate that venture capital or investment funds qualify as "individuals" under the SBIR program.

The SBIR program has fueled small business research and venture capital funding has enabled business development and commercialization, thereby strengthening the competitive free enterprise system and the United States economy. This is especially true in the capital-intensive medical device industry as such companies need to seek venture capital or other private equity to support the significant costs of research, development and commercialization of their new technologies. This will ensure that SBIR funded companies will not only have the resources but the capital to ensure the commercialization of the funded research. **Therefore, MDMA believes that the SBA should (1) provide an exclusion from affiliation with VCCs in determining small business eligibility and (2) further extend an exception to the 51% Rule to include VCCs in the definition of "individuals."**

The SBIR program was designed to tap the research and development resources of small, innovative firms. In order to achieve this mission, the program must be flexible enough to accommodate companies that rely on a variety of investors. MDMA remains committed to promoting a research funding environment that rewards the innovative sector of the health care technology world.

We appreciate the opportunity to comment on this proposed rule. If you have any questions or would like to discuss these ideas further, please contact me at 202-349-7171 or mleahey@medicaldevices.org.

Sincerely,



Mark Leahey
Executive Director
Medical Device Manufacturers Association